1. Principal Investigator or designee
   a. Submits to Office of Sponsored Programs (OSP) the proposal and “Authorization to Seek Off-Campus Funds” form (PA-005) indicating in PA-005 section 6E that the study involves Human Gene Transfer (HGT).
   b. Submits proposed research protocol to chair for departmental review.

2. Department Chair or designee
   Assures that the protocol has undergone scientific review and that the department will support the proposed research with appropriate resources.

3. Principal Investigator or designee
   Notifies the Institutional Biosafety Committee (IBC) of new HGT study by submitting the protocol and supporting documents through e-Protocol.

4. Institutional Biosafety Committee Analyst
   a. Receives notification of HGT from e-Protocol and forwards protocol to Institutional Biosafety Committee (IBC) chair.
   b. Adds HGT study is to HGT Tracking Sheet.
   c. Notifies the following individuals / offices of the impending HGT:
      i. Associate Vice President, Office of Research Compliance (or designee)
         1. For coordination of the institutional approval process.
         2. To review and ensure no conflicts of interest exist.
         3. To collaborate with Technology Commercialization Office (TCO) to review and determine if there are any potential intellectual property issues.
      ii. College of Medicine (COM) (Associate Dean for Convergent Research, or designee).
      iii. Director, Office of Sponsored Programs.

5. Institutional Biosafety Committee (Chair or other IBC member as assigned)
   a. Pre-reviews the IBC application.
   b. For investigator-initiated protocols, consider if it meets one or more of the criteria below for more in-depth review, need for additional expertise, etc.
      i. The protocol uses a new vector, genetic material, or delivery system for first-in-man testing;
      ii. The protocol relies on preclinical safety data obtained using a new preclinical model system of unknown and unconfirmed value; or
      iii. The proposed vector, gene construct, or delivery system is associated with toxicities that are not widely known and that may render it difficult for an oversight body to evaluate the protocol rigorously.
   c. For industry-sponsored protocols, cooperative-group protocols initiated by an investigator at another institution, obtain a letter from the sponsor attesting that the protocol does not meet the criteria in 5.b. above.
   d. Assigns the HGT to the IBC agenda.

6. Institutional Biosafety Committee
   a. Reviews the research protocol utilizing infectious disease and/or other consultants as required.
   b. Approves, disapproves, requires modifications, or defers research protocol.
7. Principal Investigator or designee
   a. Attends Institutional Biosafety Committee (IBC) meeting (when requested).
   b. Provides additional information as requested.
   c. Responds to any IBC concerns and/or condition.

8 Institutional Biosafety Committee
   a. Reviews principal investigator responses to any conditions set by the committee.
   b. Approves the research protocol.
   c. IBC chair, or designee, produces Human Gene Therapy Risk Summary and Risk Matrix and provides to:
      i. Institutional Review Board (IRB).
      ii. Director, Office of Research Compliance (or designee).
      iii. Associate Dean for Convergent Research, COM (or designee).

9. Principal Investigator or designee
   a. Route ICF through Office of Research Compliance (ORC) to confirm inclusion of required language and for ORC to generate Human Gene Transfer Summary.
   b. Submits application and protocol to IRB.

10. Institutional Review Board
    b. Reviews the proposed research using the usual approval criteria with the focus of the review on the human subjects involved.
    c. Utilizes consultants as necessary.
    d. Approves, Disapproves, Requires Modifications or Defers as appropriate.

11. Principal Investigator or designee
    a. Provides additional information as requested by the IRB.
    b. Addresses any concerns or conditions specified by the IRB.
    c. Route ICF and protocol, if modified, through Office of Research Compliance (ORC) to confirm inclusion of required language and for ORC to edit Human Gene Transfer Summary.

12. Institutional Review Board
    a. Reviews responses to conditions set by the committee.
    b. Issues final IRB approval of the study.
    c. Provides access to IRB Minutes and action letters to Office of Research Compliance for coordination of the institutional approval process.

13. Ohio State Office of Sponsored Programs
    a. Negotiates sponsored research agreement (if applicable) ensuring consistency with all other clinical trials.
    b. Federal Reporting Requirements
       i. Define if sponsor or institution will be responsible for reporting all significant problems, violations of the NIH Guidelines, or any significant research-related accidents and illnesses to NIH Office of Science Policy as outlined in the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules as responsibilities of the Institution in Section IV-B-1-j and of the PI in Section IV-B-7-a-(3).
       ii. Define that in the event the sponsor is determined to be the responsible reporting party, that the Ohio State IBC receives copies of all submissions and reports.
    c. Finalizes sponsored research agreement pending approval of research by Vice President for Research or provost in cases where a potential conflict of interest may exist.
14. Clinical Research Finance and Compliance (only for Comprehensive Cancer Center trials)

a. Prepares CCC HGT approval documents (i.e., CCC Trial Summary and CCC Benefit Matrix).
b. Obtains CCC Leadership approval of documents and trial.
c. Submits CCC HGT approval documents to Office of Research Compliance (ORC).

15. Associate Vice President, ORC and Associate Dean for Convergent Research, College of Medicine or designees

Prepare a Human Gene Transfer Summary and provide to the Vice President, Office for Research, or the Provost (in cases where potential conflict may exist) for review and approval.

16. Vice President for Research (or the Provost in Cases where Potential Conflict May Exist)

a. Reviews HGT Summary.
b. IF APPROVED, forwards the signed HGT Summary to the Dean, College of Medicine (or other college as appropriate), copying the following university officials to inform them of the upcoming HGT:
   i. Office of the Provost or Office of Research (if approved by the Provost).
   ii. Office of the General Counsel.
   iii. Office of Business and Finance.
   iv. Additional copy is provided to PI; PI’s department chair; Associate Vice President ORC (or designee); Associate Dean for Convergent Research, COM (or designee); Director, OSP; Ohio State Institutional Official, Chair IBC, Director of the Office of Responsible Research Practices (ORRP), and IBC analyst.
c. For trials conducted under the Comprehensive Cancer Center, also copy:
   i. CCC Director
   ii. CCC Associate Director, Clinical Research
   iii. Medical Director, Clinical Trials Office
   iv. Business Manager/Director, Clinical Research Finance and Compliance
d. IF NOT APPROVED, the Vice President for Research or Provost contacts the Associate Vice President, Office of Research Compliance (or designee) and Associate Dean for Convergent Research, COM (or designee).
e. For trials conducted under the Comprehensive Cancer Center, also copy Business Manager/Director, Clinical Research Finance and Compliance to address issues as needed.

17. Director, Ohio State Office of Sponsored Programs or designee

a. Executes sponsored research agreement (if applicable).
b. Ensures that copies of Approval Notification and HGT Summary are filed in the project files.

18. Director, Office of Responsible Research Practices or designee

a. Ensures that copies of Approval Notification and HGT Summary are filed in the IRB and IBC files for the study.
b. Ensures that copies of all Adverse Event (AE) and Serious Adverse Event (SAE) reports, as well as IBC and IRB reviews of AE and SAE reports, are provided to or accessible by the IBC and ORC.

19. IBC Analyst

a. Ensures that copies of all SAE reports are filed in IBC files.
b. Notifies ORC in the event of a reported rDNA or biohazard incident.

20. Associate Vice President, Office of Research Compliance or designee

Perform a monthly review of the open to accrual HGT trial portfolio and a quarterly review of the closed to accrual HGT trial portfolio focusing on issues of safety and compliance and their impact across all HGT trials.
21. If an AE/SAE, non-compliance or rDNA/biohazard incident report is received

a. The Office of Research Compliance will review and will notify the following individuals and provide copies of AE/SAE reports to:
   i. Chair, Institutional Biosafety Committee.
   ii. Associate Vice President, ORC (or designee).
   iii. Associate Dean for Convergent Research, COM (or designee).

b. The IBC Chair will ensure that any significant problems, violations of the NIH Guidelines, or any significant research-related accidents and illnesses are reported to OSP NIH within thirty (30) days, as mandated by the NIH Guidelines section IV-B-1-j. and section IV-B-7-a-(3).

c. Associate Vice President, ORC (or designee) and Associate Dean for Convergent Research, COM (or designee) will review reports and as appropriate notify:
   i. Vice President for Research, Office of Research
   ii. Senior Director, Media Relations (as needed) to prepare external communications regarding the events in conjunction with study Sponsor.

d. Vice President for Research will, as appropriate, inform University Executive Leadership of any significant changes or adverse events encountered with the study and take appropriate steps to ensure the safe and compliant conduct of the study.